Inspection Type

*Category:

797 Inspection

Facility Information

*Name:

DEA #:

Phone #:

e.g., 123-456-7890

*Permit Type:

*Permit Class:

*Permit #:

Inspection Type:

Inspection Date:

*Address 1:

Supervising Pharmacist:

Address 2:

Supervising Pharmacist License Number:

*City:

*State:

*Zip:

Sterile Compounding Manager / Designated Person:

*County:

Sterile Compounding Manager / Designated Person License Number:

*Type of Practice:

797 Questions

Number of PEC's:

Number of CAI's:

Number of LAFW :

Number of BSC's :

Number of IVLFZ:

Number of CACI's:

Volume Dispensed

Total prescriptions/orders filled per day:

% Sterile compounded prescriptions/orders:

% Compounded Controlled Substance Prescriptions:

% Compounded Hazardous Prescriptions:

% Compounded Veterinary Prescriptions:

Personnel

Number of Compounding Pharmacists:

Number of Compounding Technicians:

Inspection Questions

✓ Y	✕ N	! NA	! NI	Inspection Item	Comments
Set Section N/A				**Pharmacy Operations**	

1)		Does the pharmacy dispense sterile compounded preparations pursuant to a prescription/order?	
2)		Does the pharmacy compound an approved commercially available product? • The compounded preparation produces a clinical difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner.	
3)		Does the pharmacy compound Category 1 sterile products?	
4)		Does the pharmacy compound Category 2 sterile products?	
5)		Are Category 2 CSPs compounded from non-sterile components?	
6)		Does the pharmacy compound Category 3 sterile products?	
7)		Does the pharmacy compound Immediate-Use sterile products?	
8)		Does the pharmacy perform compounding with hazardous drugs?	
9)		Does the pharmacy perform central prescription filling	
10)		Pharmacy has Policy/Procedure manual to outline and explain all components and operations of compounding sterile products.	
11)		Is the pharmacy licensed in other states?	
12)		Does the pharmacy hold any accreditations?	
13)		Has the pharmacy been inspected by any other agencies or organizations?	

14)		Is the pharmacy under any restrictions, limitations, or waivers by any state the pharmacy is licensed in?	
15)		All pharmacists and technicians hold an active registration with the Kentucky Board of Pharmacy.	

Set Section N/A

Personnel Training and Evaluation

16)		Personnel who compound or have direct oversite of compounding personnel, have demonstrated knowledge of principles and completed competency skills in at least the following. Must be completed initially and at least every 12 months after. (USP 797 - (2.1) • Cleaning and disinfection • Calculations, measuring and mixing • Use of equipment • Documentation of the compounding process • Principles of HEPA filtered unidirectional airflow in ISO 5 • Proper use of PEC's • Principles of movement of materials and personnel within the compounding area	
17)		Before beginning to compound or have direct oversite over compounding personnel, personnel have successfully completed an initial garbing competency evaluation 3 separate times in succession. (USP 797 - (2.2) • Three separate and complete full hand hygiene and full garbing procedure • Three separate gloved fingertip and thumb sampling of both hands after garbing • Visual evaluation during hand hygiene and garbing • 0 CFU's total from both hands	
18)		Compounding personnel have completed garbing and hand hygiene competency evaluations every six months for Category 1 and Category 2 compounds. (USP 797 - (2.2) • 0 CFU's total from both hands	

19)		Personnel compounding Category 3 compounds have completed garbing and hand hygiene competency evaluations every 3 months. (USP 797 - (2.2) • 0 CFU's total from both hands	
20)		Personnel who have direct oversite of compounding personnel, but do not compound, have completed hand hygiene and garbing competency evaluations every 12 months. (USP 797 - (2.2) • 0 CFU's total from both hands	
21)		Personnel compounding Category 1 and Category 2 compounds have completed an aseptic manipulation competency evaluation every 6 months. (USP 797 - (2.3) • Visual observation • Media-fill testing • Gloved fingertip and thumb sampling after media fill ◦ No more than 3 CFU's total from both hands • Surface sampling of the direct compounding area after media fill ◦ No more than 3 CFU's in ISO class 5	
22)		The pharmacy has documentation of any failed hand hygiene and garbing competency evaluation. (USP 797 - (2.2)Box 1	
23)		Personnel compounding Category 3 compounds have completed an aseptic manipulation competency evaluation every 3 months. (USP 797 - (2.3) • Visual observation • Media-fill testing • Gloved fingertip and thumb sampling after media fill ◦ No more than 3 CFU's total from both hands • Surface sampling of the direct compounding area after media fill ◦ No more than 3 CFU's in ISO class 5	

24)		Compounding personnel or personnel who have direct oversite of compounding personnel, have completed an initial aseptic manipulation competency evaluation. (USP 797 - (2.3) • visual observation • Media-fill testing • Gloved fingertip and thumb sampling after media fill • ◦ No more than 3 CFU's total from both hands • Surface sampling of the direct compounding area after media fill • ◦ No more than 3 CFU's in ISO class 5	
25)		Personnel who have direct oversite of compounding personnel, but do not compound, have completed an aseptic manipulation competency evaluation every 12 months. (USP 797 - (2.3) • Visual observation • Media-fill testing • Gloved fingertip and thumb sampling after media fill • ◦ No more than 3 CFU's total from both hands • Surface sampling of the direct compounding area after media fill • ◦ No more than 3 CFU's in ISO class 5	
26)		Media-fill test simulate the most difficult and challenging aseptic compounding procedures and capture elements that could potentially affect the sterility of the CSP. (USP 797 - (2.3) • Factors associated with length of process • Number of aseptic additions or transfers • Number, type, and complexity of manipulations • Number of personnel in the buffer room or SCA	
27)		The pharmacy has documentation of any failed aseptic manipulation competency evaluation. (USP 797 - (2.3)	
28)		Training policy outlined in the pharmacies policy and procedure manual. (USP 797 - (20) Box 2	

Set Section N/A		Personal Hygiene and Garbing	
29)		Before entering a compounding area, individuals must remove any items that are not easily cleanable or are not necessary for compounding. (USP 797 - (3.1) • Remove personal outer garments, cosmetics, exposed jewelry/piercings, artificial nails • No earbuds or headphones • No electronic devices that are not necessary for compounding • Wipe eyeglasses if worn The designated person may permit accommodations as long as the quality of the CSP and environment will not be affected.	
30)		Hand washing includes removing debris under fingernails, washing hands and forearms with soap for at least 30 seconds, and low-lint disposable towels or wipes to dry hands. (USP 797 - (3.2) • If hand washing is performed outside of the ante-room, alcohol-based hand rub must be applied before donning garb. (USP 797 - (3.3)	
31)		Garb must be donned and doffed in an order that reduces risk of contamination and is documented in the policies and procedures. (USP 797 - (3.3)	
32)		Category 1 and Category 2 garbing includes the following. (USP 797 - (3.3) • Low-lint garment with sleeves that fit snugly around the wrists with an enclosed neck • Low-lint covers for shoes • Low-lint cover for head that covers the hair and ears, and if applicable, a cover for facial hair. • Low-lint face mask • Sterile powder-free gloves	

33)		Category 3 garbing includes the following additional requirements. (USP 797 - (3.3) • No exposed skin in the buffer room • All low-lint outer garb must be sterile • Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validation cycle	
34)		Alcohol based hand rub is applied before donning sterile gloves. (USP 797 - (3.2) • Sterile gloves are donned in a classified room or SCA.	
Set Section N/A		**Facility Design - Cleanroom Suite**	
35)		The pharmacy has an ISO classified anteroom and buffer room separated from the surrounding unclassified areas of the facility by fixed walls and doors with controls in place to minimize the flow of lower-quality air in the more controlled areas. USP 797 - (4.2.1)	
36)		The anteroom and buffer room is supplied with High-efficiency Particulate Air Filtration (HEPA). (USP 797 - (4.2.1) • HEPA filters are located in ceiling • Air returns in the cleanroom suite are low on the wall. • If air returns are not low on the wall, a visual smoke study has been performed to show the absence of stagnant airflow.	
37)		The anteroom has a line of demarcation to separate the clean side from the dirty side. (USP 797 - (4.2.1)	
38)		A sink with hot and cold running water is available for hand hygiene is located in the ante room. (USP 797 - (4.4) • If located outside of ante room, it is in a clean space to minimize the risks of bringing contaminants into the anteroom.	
39)		All surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area must be smooth, impervious, free from cracks and crevices, and nonshedding. (USP 797 - (4.3.1)	

40)		Floors must include coving to the sidewall, or the juncture between the floor and the wall must be caulked. (USP 797 - (4.3.1)	
41)		Walls must be constructed of, or may be covered with, durable material (e.g., epoxy painted wall or heavy-gauge polymer) and the integrity of the surface must be maintained. (USP 797 - (4.3.1)	
42)		If ceilings consist of inlaid panels, the panels must be caulked around each panel to seal them to the support frame. (USP 797 - (4.3.1)	
43)		Junctures between the ceiling and the walls and between the walls and floor must be sealed to eliminate cracks and crevices. (USP 797 - (4.3.1)	
44)		Doors in the anteroom and buffer room are coordinated to prevent both being open at the same time by interlocking, training, or signage (USP 797 - (4.2.1) • No tacky mats in ISO rated areas.	
45)		Pass-through chambers are coordinated to prevent both from being open at the same time by interlocking, training, or signage. USP 797 - (4.2.1)	
46)		Buffer room does not contain plumbed water sources such as a sink, eyewash station, showers, or floor drains (USP 797 - (4.4)	
Set Section N/A		**Environmental Controls - cleanroom suite**	
47)		Certification of the cleanroom suite must be performed initially and recertification must be performed at least every 6 months and includes: (USP 797 - (5) • Airflow testing • HEPA filter integrity testing • Total particle count testing • Dynamic airflow smoke pattern test in each PEC	
48)		Total airborne particle count testing is conducted in all classified areas every 6 months. (USP 797 - (5.1)	
49)		Anteroom is certified as ISO 8 having less than 3,520,000 particles, greater than or equal to 0.5 microns, per cubic meter of air. (USP 797 - (4.1.2) - (Table 4)	

50)		Buffer room is certified as ISO 7 having less than 352,000 particles, greater than or equal to 0.5 microns, per cubic meter of air. (USP 797 - (4.1.2) - (Table 4)	
51)		A minimum differential positive pressure of 0.02 inch water column is required between adjacent ISO-classified areas. (USP 797 - (4.2.5) • Anteroom is at least 0.02" w.c. positive pressure to unclassified area. • Buffer room is at least 0.02" w.c. positive pressure to anteroom • Pressures are continuously monitored by a pressure differential monitoring device. • The results from the pressure monitoring device are reviewed and documented at least daily.	
52)		ISO 7 buffer room is certified as having a minimum of 30 total HEPA filtered Air Changes Per Hour (ACPH). (USP 797 - (4.2.4) • At least 15 ACPH of thee total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling. • The HEPA filtered air from the PEC, when added to the HVAC supplied HEPA filtered air, must increase the total HEPA filtered ACPH to at least 30 ACPH. • The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report.	
53)		ISO 8 anteroom is certified as having a minimum of 20 total HEPA filtered ACPH. (USP 797 - (4.2.4) • At least 15 ACPH of the total air change rate in a room must come from the HVAC through HEPA filters located in the ceiling • The total ACPH must be documented on the certification report.	
54)		All HEPA filters in the cleanroom suite are leak tested. (USP 797 - (5)	

55)		The temperature and humidity of each room in the cleanroom suite is monitored. (USP 797 - (4.2) • Temperature should be 20 degrees C (68 degrees F) or cooler and a relative humidity of 60%. • Readings are documented at least daily or stored on continuous reading device. • Must be controlled by HVAC system • No free-standing air conditioners, humidifiers, or dehumidifiers • Monitoring devices must be verified for accuracy every 12 months or as required by manufacturer.	
56)		Microbiological air and/or surface monitoring is conducted in all classified areas during dynamic operations. (USP 797 - (6.1) • In conjunction with the certification of new facilities and equipment • In response to identified problems (e.g., positive growth in sterility tests of CSP's) • In response to identified trends • In response to changes that could impact the sterile compounding environment.	
57)		Viable air sampling is conducted in all classified areas during dynamic operating conditions. (USP 797 - (6.1) • Sampling is performed using a volumetric impaction air sampler • At least 1 cubic meter or 1000 Liters of air is sampled. • Diagram of sampling locations and procedures for collecting samples (frequency, time of day, action levels)	
58)		Pharmacies that compound category 1 and category 2 compounds, viable air sampling is performed every 6 months. (USP 797 - (6.2.1)	
59)		Category 3 compounding pharmacies perform monthly viable air sampling. (USP 797 - (6.2.1) • Must be completed at least 30 days prior to the commencement of any category 3 compounding.	

60)		Viable air sampling procedures are in compliance with Active Air Sampling Procedures for Viable Airborne Monitoring outlined in USP 797. (USP 797 - (Box 5)	
61)		A general microbiological growth media that supports the growth of bacteria and fungi is used. (USP 797 - (6.2.2) • COA's from the manufacturer verify that the sampling media devices meet the expected growth promotion, pH, and sterilization requirements	
62)		Total CFU count of viable air samples at each ISO rated location did not exceed action levels. (USP 797 - (Table 7) • ISO 5 No more than 1 • ISO 7 No more than 10 • ISO 8 No more than 100	
63)		If the total CFU count of viable air samples at each ISO rated location exceeded action levels. (USP 797 - (6.2.3) • Cause investigated • Corrective action taken • Data collected in response to corrective action must be reviewed to confirm the actions have been effective. • Attempt made to identify any microorganism recovered to genus level • Corrective action should include resampling of failed areas to confirm corrective action was successful	
64)		Surface sampling includes diagram of sampling locations and procedures for collecting samples (frequency, time of day, action levels) (USP 797 - (6.1)	
65)		Surface sampling is conducted in each of the following. (USP 797 - (6.3.1) • Each ISO rated area • Pass through chambers • Equipment contained within the PEC • Staging or work areas near the PEC • Frequently touched surfaces	

66)		Pharmacies that compound category 1 and category 2 compounds, surface sampling is conducted monthly. (USP 797 - (6.3.1)	
67)		Category 3 compounding pharmacies perform surface sampling weekly and prior to assigning extended beyond use dating. (USP 797 - (6.3.1) • Conducted in the PEC at the end of each batch before cleaning and disinfection.	
68)		Surface sampling is in compliance with surface sampling procedures outlined in USP 797. (USP 797 - (Box 6)	
69)		Surface sampling media contains a general microbial growth media (e.g., TSA) supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). (USP 797 - (6.3.2) • COA's from the manufacturer verify that the sampling media devices meet the expected growth promotion, pH, and sterilization requirements	
70)		Total CFU count of each surface location does not exceed action levels. (USP 797 - (Table 8) • ISO 5 No more than 3 • ISO 7 No more than 5 • ISO 8 No more than 50	
71)		If the total CFU count of surface sample locations exceed action levels. (USP 797 - (6.3.3) • Cause investigated • Corrective action taken • Data collected in response to corrective action must be reviewed to confirm the actions have been effective. • Attempt made to identify any microorganism recovered to genus level	
72)		The designated person is familiar with viable air and surface monitoring requirements, interpretation of the results, ensures all testing is performed appropriately, and evaluates results to detect issues or trends. (USP 797 - (4.2) (6.1)	

Set Section N/A

Pharmacy Operations

73)		The PEC(s) is located in an ISO 7 buffer room of a clean room suite that minimizes conditions that could increase the risk of microbial contamination. (USP 797 - (4.2.1) • Away from strong air currents from open doors. • Away from air streams from the HVAC system that could disrupt unidirectional airflow of an open faced PEC.	
74)		PEC(s) is free from visible damage and unsanitary conditions. (USP 797 - (4)	
75)		PEC(s) have been certified within the last six months to meet ISO 5 having less than 3,520 particles, greater than or equal to 0.5 microns, per cubic meter of air. (USP 797 - (4.2.3) • Dynamic airflow smoke pattern test performed to demonstrate unidirectional airflow. • HEPA filter integrity testing conducted.	
76)		Only equipment necessary for performing compounding activities is permitted in PEC. (Usp 797 - (4.5)	
77)		Viable air sampling is conducted in PEC(s) during dynamic operating conditions. (USP 797 - (6.1) • Sampling is performed using a volumetric impaction air sampler • At least 1 cubic meter or 1000 Liters of air is sampled. • Diagram of sampling locations and procedures for collecting samples (frequency, time of day, action levels)	
78)		Pharmacies that compound category 1 and category 2 compounds, viable air sampling in PEC(s) is performed every 6 months. (USP 797 - (6.2.1)	
79)		Category 3 compounding pharmacies perform monthly viable air sampling in PEC(s). (USP 797 - (6.2.1) • Must be completed at least 30 days prior to the commencement of any category 3 compounding.	

80)		Viable air sampling procedures are in compliance with Active Air Sampling Procedures for Viable Airborne Monitoring outlined in USP 797. (USP 797 - (Box 5)	
81)		Total CFU count of viable air samples taken in the PEC did not exceed action levels. (USP 797 - (Table 7) • ISO 5 No more than 1	
82)		If the total CFU count of viable air samples taken in the PEC(s) exceeded action levels. (USP 797 - (6.2.3) • Cause investigated • Corrective action taken • Data collected in response to corrective action must be reviewed to confirm the actions have been effective. • Attempt made to identify any microorganism recovered to genus level • corrective action should include resampling of failed areas to confirm corrective action was successful	
Set Section N/A		**Primary Engineering Control(s)**	
83)		Surface sampling is conducted monthly for pharmacies that compound category 1 and category 2 compounds,. (USP 797 - (6.3.1) • Includes equipment contained in PEC(s)	
84)		Surface sampling weekly and prior to assigning extended beyond use dating for category 3 compounding pharmacies. (USP 797 - (6.3.1) • Conducted in the PEC at the end of each batch before cleaning and disinfection. • Includes equipment contained in PEC(s)	
85)		Surface sampling is in compliance with Surface Sampling Procedures outlined in USP 797. (USP 797 - (Box 6	
86)		Total CFU count of each surface location in PEC(s) did not exceed action levels. (USP 797 - (Table 8) • ISO 5 No more than 3	

87)		If the total CFU count of surface sample locations exceed action levels In PEC(s). (USP 797 - (6.3.3) • Cause investigated • Corrective action taken • Data collected in response to corrective action must be reviewed to confirm the actions have been effective. • Attempt made to identify any microorganism recovered to genus level	
88)		Pharmacy is utilizing a RABS (CAI) to prepare Category 2 CSP's • it is located in a cleanroom suite (USP 797 - (4.2.3) • Sterile gloves are worn over the gloves attached to the RABS sleeve. (USP 797 - (3.3) • Recovery time after opening the transfer chamber to achieve ISO 5 is documented. (USP 797 - (4.2.3)	
89)		If the PEC(s) used for non-sterile compounding is placed in the same room as the PEC(s) for sterile compounding, they are at least 1 meter apart. (USP 797 - (4.2.1) • Particle generating activity must not be performed when sterile compounding is in process	
Set Section N/A		**PEC located in a Segregated Compounding Area (SCA)**	
90)		All surfaces (walls, floors, counters, equipment) is clean, uncluttered and dedicated to compounding. (USP 797 - (4.3.2) (4.2.1) • The area within 1 meter of the PEC is dedicated only for sterile compounding • The compounding area shall have cleanable surfaces to include walls, ceilings, and floors. (34-23-152)	
91)		Located away from unsealed windows or doors that connect to the outdoors, restrooms, warehouses, or food preparation areas. (USP 797 - (4.2.1)	
92)		Access to the SEC is restricted to authorized personnel and required materials. (USP 797 - (4.2.1)	

93)		The hand washing sink is at least 1 meter away from the PEC. (USP 797 - (4.4) • The sink may be either inside the SCA or in close proximity to the SCA.	
94)		The PEC inside the SCA is in a location that minimizes conditions that could increase the risk of microbial contamination. (USP 797 - (4.2.1) • he PEC is free from visible damage and unsanitary conditions (USP 797 - (4)	
95)		PEC(s) have been certified within the last six months to meet ISO 5. (USP 797 - (4.2.3) • Dynamic airflow smoke pattern test performed to demonstrate unidirectional airflow. • HEPA filter integrity testing conducted.	
96)		Only equipment necessary for performing compounding activities is permitted in PEC. (USP 797 - (4.5)	
97)		All garbing requirements are followed by personnel compounding sterile products. (USP 797 - (3.3)	
98)		Viable air sampling in PEC(s) located in the segregated compounding area is performed every 6 months. (USP 797 - (6.2.1)	
99)		Viable air sampling is conducted in PEC(s) during dynamic operating conditions. (USP 797 - (6.1) • Sampling is performed using a volumetric impaction air sampler • At least 1 cubic meter or 1000 Liters of air is sampled. • Diagram of sampling locations and procedures for collecting samples (frequency, time of day, action levels)	
100)		Total CFU count of viable air samples taken in the PEC did not exceed action levels. (USP 797 - (Table 7) • ISO 5 No more than 1	
101)		Viable air sampling procedures are in compliance with Active Air Sampling Procedures for Viable Airborne Monitoring outlined in USP 797. (Box 5)	

102)		If the total CFU count of viable air samples taken in the PEC(s) exceeded action levels. (USP 797 - (6.2.3) • Cause investigated • Corrective action taken • Data collected in response to corrective action must be reviewed to confirm the actions have been effective. • Attempt made to identify any microorganism recovered to genus level • corrective action should include resampling of failed areas to confirm corrective action was successful	
103)		Surface sampling is conducted monthly. (USP 797 - (6.3.1) • Includes equipment contained in PEC(s)	
104)		Total CFU count of each surface location in PEC(s) did not exceed action levels. (USP 797 - (Table 8) • ISO 5 No more than 3	
105)		Surface sampling is in compliance with Surface Sampling Procedures outlined in USP 797. (USP 797 - (Box 6)	
106)		If the total CFU count of surface sample locations exceed action levels In PEC(s). (USP 797 - (6.3.3) • Cause investigated • Corrective action taken • Data collected in response to corrective action must be reviewed to confirm the actions have been effective. • Attempt made to identify any microorganism recovered to genus level	
107)		The designated person is familiar with viable air and surface monitoring requirements, interpretation of the results, ensures all testing is performed appropriately, and evaluates results to detect issues or trends. (USP 797 - (4.2) (6.1)	
108)		Compounded sterile products compounded in the SCA are given a beyond use date of 12 Hr. room temperature and 24 Hrs. refrigerated. (USP 797 - (Table 12)	

Set Section N/A **Cleaning, Disinfecting, Applying Sporicidal Disinfectants and Sterile 70% IPA. (7)**

109)		All cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. (USP 797 - (7)	
110)		Pharmacies compounding Category 1 and Category 2 CSP's, the PEC and equipment inside the PEC is cleaned and disinfected daily when compounding occurs. (USP 797 - (7) (Table 10) • 70% sterile IPA is applied after cleaning and disinfecting • All cleaning, disinfecting and sporicidal agents used in PEC are sterile (USP 797 - (7.1.1) • Sporicidal disinfectant applied Monthly. • Manufacturers directions for contact time is followed.	
111)		Category 3 compounding pharmacies clean and disinfect the PEC and equipment inside the PEC daily when compounding occurs. (USP 797 - (7) (Table 10) • 70% sterile IPA is applied after cleaning and disinfecting • All cleaning, disinfecting and sporicidal agents used in PEC are sterile (USP 797 - (7.1.1) • Sporicidal disinfectant applied Monthly. • Manufacturers directions for contact time is followed.	
112)		Pharmacies compounding Category 1 and Category 2 CSP's, work surfaces, floors, sink(s) and pass-through chamber(s) are cleaned and disinfected daily when compounding occurs. (USP 797 - (7) (Table 10) • Sporicidal disinfectant applied Monthly. • Manufacturers directions for contact time is followed.	
113)		Category 3 compounding pharmacies perform daily cleaning and disinfecting of work surfaces, floors, sink(s) and pass-through chambers daily. (USP 797 - (7) (Table 10) • Sporicidal disinfectant is applied Weekly • Manufacturers direction for contact time is followed.	

114)		Pharmacies compounding Category 1, Category 2, and Category 3 CSP's, walls, doors, ceiling, storage shelving, bins, and equipment is cleaned and disinfected monthly. (USP 797 - (7) (Table 10) • Ceilings of SCA are only required to be cleaned and disinfected when visibly soiled or when surface contamination is suspected. • Manufacturers direction for contact time is followed.	
115)		All cleaning and disinfecting supplies (wipers, sponges, pads, and mop heads) must be low lint. (USP 797 - (7.1.2)	

Set Section N/A

Compounding Procedures

116)		Compounding personnel verify that CSP components are the correct identity, quantity, storage conditions, and within expiration date before compounding. (USP 797 - (9.3.3)	
117)		Compounding was observed or simulated during the inspection.	
118)		Before items are introduced into the clean side of the ante room, placed into pass-through chambers, or brought into the SCA, they are wiped with a disinfectant. (USP 797 - (8.1) • Sporicidal disinfectant, EPA-registered disinfectant or sterile 70% IPA is used. • Low lint wipers are used by personnel wearing gloves.	
119)		The PEC is disinfected with sterile 70% IPA before initiating compounding. (USP 797 - (7	
120)		Before items are introduced into the PEC, items are wiped with sterile 70% IPA and allowed to dry. (USP 797 - (8.2)	
121)		Critical sites (vial stoppers, ampule necks, and intravenous bag septums) are wiped with sterile 70% IPA. (USP 797 - (8.3)	

122)		Compounding personnel use appropriate aseptic technique. (USP 797 - (2) • Proper use of 1st air • Gloves are disinfected with sterile 70% IPA before compounding and regularly throughout the compounding process.	
Set Section N/A		**Equipment, Supplies, and Components**	
123)		The equipment used in compounding is appropriate, clean and capable of operating properly. (USP 797 - (9.1) • Equipment is of suitable composition and not reactive or sorptive. • Calibration and maintenance is based on manufacturer's recommendations. • Daily record of accuracy assessment is maintained.	
124)		Automated Compounding Devices (ACD's) have an accuracy assessment conducted each day before being used to compound CSP's. (USP 797 - (9.1) • Daily record maintained	
125)		Equipment designed to deliver a specific volume of solution(s) and/or scales have an accuracy assessment conducted each day before being used to compound CSP's. (USP 797 - (9.1) / (34-23-150) • Daily record maintained	
126)		All Active Pharmaceutical Ingredients (API's) are evaluated for suitability for use in sterile drug preparations. (USP 797 - (9.3.1) • Components or API's are NOT labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or an equivalent statement.	

127)		Active Pharmaceutical Ingredients (API's) and Components: (USP 797 - (9.3.1) • Comply with the criteria in the USP-NF monograph if one exists • Have a Certificate of Analysis (COA) that includes the specifications and meets the expected quality. • Manufactured in an FDA registered facility • In expiry date and stored within manufacturers guidelines • Stored in a manner to prevent contamination, mix-ups, and deterioration	
128)		Components that cannot be obtained from FDA-registered facilities, the compounding facility must establish the identity, strength, purity, and quality of the ingredients. (USP 797 - (9.3.1)	
129)		The temperature and humidity where all API's and components are stored is monitored. (USP 797 - (9.3.4) • Daily log maintained • Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months.	
130)		Any API or component found to be of unacceptable quality is labeled as rejected and segregated from active stock. (USP 797 - (9.3.3) If a component is transferred from the original container, the new container has the following information: (34-23-157) • Component name • Manufacturer • Lot number • Expiration date	
Set Section N/A		**Compounding Records (CR), Visual Inspection, and Final Check**	

131) A master formulation (MFR) is created for all CSP's prepared from nonsterile ingredients or CSP's prepared for more than one patient. (USP 797 - (11.1)

- Name, strength or activity, and dosage from of the CSP
- Identities and amounts of all ingredients
- Type and size of container closure system
- Complete instructions for preparing the CSP, including equipment, supplies, description of the compounding steps, and any special precautions
- Physical description of the final CSP
- BUD and storage requirements
- Reference source to support the stability of the CSP
- Quality control procedures (e.g., pH testing, filter integrity testing)
- Other information needed to describe the compounding process to ensure repeatability

132) A Compounding Record (CR) is created for all Category 1, Category 2, and Category 3 CSP's. (USP 797 - (11.2)

- A prescription or medication order or label may serve as the CR
- Required information may be stored electronically

133) The Compounding Record (CR) contains the following information. (USP 797 - (11.2)

- Name, strength or activity, and dosage form of the CSP
- Date and time of preparation of the CSP
- Assigned internal identification number (Prescription, order, lot number)
- A method to identify the individuals involved in the compounding process
- Name of each component
- Weight or volume of each component
- Strength or activity of each component
- Total quantity compounded
- Final yield (quantity, containers, number or units)
- Assigned BUD and storage requirements
- Results of QC procedures
-
  - Vendor, lot number, and expiration date for each component for CSP's prepared for more than one patient and for CSP's prepared from nonsterile ingredients
  - MFR reference for the CSP
  - Calculations made to determine and verify quantities and/or concentrations of components

134) A visual inspection of the final compounded product is performed. (USP 797 - (12.1)

- Physical appearance (particulate matter, discoloration)
- Container closure integrity

135) The label on the CSP contains the following. (680-x-2-.13) (USP 797 - (13)

- Name and address of the dispensing pharmacy if a CSP is to be sent outside of the facility
- Directions for use
- Assigned internal identification number (prescription, barcode, lot number)
- Active ingredients and their amounts, activities, or concentration
- Storage conditions
- Beyond Use Date
- Dosage form
- Total amount or volume
- Type of dose container (single, multiple)
- Routes of administration
- Special handling instructions and warning statements

136) A final verification and check is performed by a pharmacist before the CSP is dispensed. (680-x-2-.14e) (USP 797 - (12) - (12.1)

- Visual check of the CSP and container
- Prescription/orders and label
- Compounding record (medications, amounts, calculations, quality control)

137) If a CSP is dispensed or administered before the results of release testing (endotoxin and sterility testing) are known, the following procedures are in place. (USP 797 - (18.1)

- Immediately notify the prescriber of the failure
- Recall any unused dispensed CSP's and quarantine any remaining stock
- Investigate if other lots are affected
- Procedure to determine the distribution of any affected CSP
- Procedure to identify patients who may have received CSP
- Procedure to investigate and document the reason for the failure

138)		The pharmacy has a SOP for handling complaints such as quality, labeling, or possible adverse reactions. (USP 797 - (18.2) • Investigation into the cause of the problem • Corrective action • Documentation (nature, date received, response)	

Set Section N/A	**Product Dating / Beyond Use Dates**	
139)	Compounded products are assigned beyond use dates in compliance with USP 797 limits. (Table 12 / Table 13 / Table 14)	
140)	A manufactured single dose container may be used up to 12 hrs. after initial entry if entered in an ISO 5. (USP 797 - (15.1)	
141)	Opened single dose ampules are not stored. (USP 797 - (15.1)	
142)	Manufactured multiple-dose containers are given a beyond use date of 28 days after initial entry if entered in ISO 5. (USP 797 - (15.2)	
143)	Manufactured pharmacy bulk packages are used according to the manufacturer's labeling and entered in ISO 5. (USP 797 - (15.3)	
144)	A compounded multiple dose product that contains a preservative must be compounded as a Category 2 or Category 3 compound, pass antimicrobial effectives testing in accordance with <51> and have a container closure integrity test conducted. (USP 797 - (14.5) • Antimicrobial effectiveness testing is conducted once for each formulation in the particular container closure system in which it will be packaged. • antimicrobial effectiveness testing results from an FDA-registered facility or published in peer-reviewed literature sources if the formulation and container closure system are exactly the same. • Antimicrobial effectiveness testing may be performed on a low concentration and on a high concentration of the active ingredient	

145)		Nonpreserved compounded multiple-dose aqueous topical and topical ophthalmic products, antimicrobial effectiveness testing is not required if. (USP 797 - (14.5) • Prepared as a Category 2 or Category 3, and • For use by a single patient, and • Labeled to indicate that once opened, it must be discarded after 24 hr. room temperature once opened and 73 hr. when refrigerated.	
146)		Compounded stock solutions and compounded single dose products. (USP 797 - (16.2) • Must be entered in ISO and stored under conditions BUD is based. • May be used for compounding up to 12 hrs. or its assigned BUD and remainder discarded. • The time limit for entering or puncturing is not intended to restrict the final BUD of the CSP.	
Set Section N/A		**Extended Beyond Use Dating / Non-Sterile Components**	
147)		If preparing Category 2 or Category 3 CSP's from nonsterile components, presterilization procedures, such as weighing and mixing, are completed in an ISO 8 or better environment. (USP 797 - (4.2.6) • Performed in a containment ventilated enclosure (CVE), single use containment glove bag, BCS, or CACI. • The CVE used is certified at least every six months.	
148)		Injectable CSP's that contain nonsterile components or that come in contact with nonsterile devices (e.g., containers, tubing) during any phase of the compounding process are sterilized within 6 hr. after completing the preparation. (USP 797 - (10)	

149)		Sterility testing is performed on Category 2 CSP's assigned a BUD that requires sterility testing. (USP 797 - (12.2) • Sterility testing is performed according to <71> • Appropriate number of CSP's are sent for testing. • Or a validated alternative method (see 1223) that is not inferior to <71>.	
150)		Bacterial endotoxin testing is performed on Category 2 injectable CSP's compounded from one or more nonsterile components and assigned a BUD that requires sterility testing. (USP 797 - (12.3) • In the absence of a bacterial endotoxin limit in an official USP-NF monograph, must not exceed limit calculated in <85> for the appropriate route of administration for humans.	
151)		Depyrogenation by dry heat. (USP 797 - (10.1) • Glass, metal, or other thermostable containers that come in contact with the CSP are depyrogenated by dry heat. (9.2) • Duration and exposure period must include sufficient time for the items to reach the depyrogenation temperature. • The effectiveness of the cycle is verified using endotoxin challenge vials (ECV's) initially and at least once annually after.	

152) Sterilization by filtration. (USP 797 - (10.2)

- Sterilizing filter are 0.22 micron or smaller, sterile, depyrogenated and appropriate for pharmaceutical use.
- Chemically and physically compatible with all ingredients of the CSP
- Filters are certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas Diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSP will be filtered (pressure, flow rate, volume)
- Filters do not contain a label that states "for laboratory use only" or similar wording.
- Each filter used to sterilize the CSP must undergo the manufacturers recommended integrity testing.

153) Sterilization of CSP's by steam heat. (Usp 797 - (10.3)

- CSP's must be directly exposed to steam under adequate pressure for the length of time necessary (e.g., 20-60 minutes at 121 degrees saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized)
- CSP must be placed to allow steam to reach the CSP without entrapment of air and must include sufficient time for the entire contents of the CSP to reach sterilizing temperature.
- Immediately before filling containers that will be steam sterilized, solutions must be passed through a filter with a nominal pore size of not larger that 1.2 micron for removal of particulate matter.
- The effectives of steam sterilization must be verified with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus Stearothermophilus.

154) Sterilization by dry heat. (USP 797 - (10.4)

- The duration of the exposure period must include sufficient time for the entire contents of the CSP to reach sterilizing temperature and remain for the duration of the sterilizing period.
- Immediately before filling containers that will be sterilized by dry heat, solutions must be passed through a filter with a nominal pore size of not larger that 1.2 micron for removal of particulate matter.
- The dry heat oven must be certified and equipped with temperature controls and a timer.
- The effectives of dry heat sterilization must be verified with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus Astophaeus.

155) Each time a Category 3 CSP is prepared, sterility testing is performed. (USP 797 - (14.4.4)

- Sterility testing is performed according to <71>
- Appropriate number of CSP's are sent for testing.
- Or a validated alternative method (see 1223) that is not inferior to <71>.

156) Each time a Category 3 CSP is prepared, bacterial endotoxin testing is performed. (USP 797 - (14.4.4)

- In the absence of a bacterial endotoxin limit in an official USP-NF monograph, must not exceed limit calculated in <85> for the appropriate route of administration for humans.

157)		The BUD assigned to Category 3 CSP's must be supported by stability data obtained using a stability-indicating analytical method validated based on characteristics described in <1225>. (USP 797 - (14.4.3) • Able to distinguish the active ingredient from its degradants and impurities (e.g., by forced degradation studies) and quantify the amount of the active ingredient. • Must be prepared according to the exact formulation from which the stability data are derived and same container closure system. • Documentation of the stability study, description of methodology, validation of the method, the stability-indicating analytical method, and all results of the study.	
158)		If the Category 3 CSP is an injection or ophthalmic solution, particulate-matter testing has been conducted once for each formulation and container closure system. (USP 797 - (14.4.3)	
159)		Category 3 CSP's do not exceed the BUD's permitted by USP 797. (USP 797 - (Table 14	
Set Section N/A		**Hazardous Drugs USP 800**	
160)		For final dosage forms of hazardous drugs that do not require further manipulation and are not required to follow the containment requirements of USP 800, an assessment of risk with alternative containment strategies/and or work practices has been performed. (USP 800 - (2), (Box 1) • Type of HD • Dosage form • Risk of exposure • Packaging • Manipulation • Reviewed every 12 months	

161) Antineoplastic HDs and all HD API's are unpacked in an area that is neutral/normal or negative pressure areas. (USP 800 - (5.1) / (10)

- PPE, including chemotherapy gloves must be worn when unpacking antineoplastic and API HDs.
- HDs are delivered to the storage area immediately after unpacking

162) Antineoplastic HD's requiring manipulation and any HD API are stored separately from non-HDs. (USP 800 - (5.2)

- Stored in an externally ventilated room
- Negative pressure room with at least 12 air changes per hour
- Dedicated refrigerator

163) The pharmacy has a hazard communication program to ensure worker safety during all aspects of HD handling. (USP 800 - (8)

- A written plan that describes how the standard will be implemented
- Have SOPs for proper labeling, transport, storage, and disposal of HDs
- Have an Safety Data Sheet (SDS) for each hazardous chemical they use and are readily accessible to personnel during each work shift.
- Personnel who may be exposed to hazardous chemicals when working must be provided information and training before being able to work with hazardous chemicals
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

164)		All personnel who handle HDs have received initial training and competency evaluations and at least every 12 months after on the following. (USP 800 - (9) • Overview of entity's list of HDs and their risks • Review of the entity's SOP's related to handling of HDs • Proper use of PPE • Proper use of equipment and devices • Response to known or suspected HD exposure • Spill management • Proper disposal of HDs and trace contamination	
165)		The surfaces of ceilings, walls, floor, fixtures, shelving, counters and cabinets where hazardous CSPs are compounded are smooth, impervious, free from cracks and crevices and non-shedding. (USP 800 - (5.3.1)	
166)		Anteroom is certified as (USP 800 - (5.3.2) • ISO 7 having less than 352,000 particles, greater than or equal to 0.5 microns, per cubic meter of air. • certified as having a minimum of 30 total HEPA filtered Air Changes Per Hour. • Has at least 0.02" w.c. positive pressure to the unclassified area and pressure is reviewed and documented daily. Certification is conducted every six months	
167)		The HD buffer room is certified as having the following : (USP 800 - (5.3.2) • ISO 7 having less than 352,000 particles, greater than or equal to 0.5 microns, per cubic meter of air. • A minimum of 30 total HEPA filtered air changes per hour • Externally vented • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas and pressure is reviewed and documented daily. • Certification is conducted every six months	

168) The C-SCA - Containment Segregated Compounding Area is certified as having the following. (USP 800 (5.3.2)
- Fixed walls
- Negative pressure between 0.01" and 0.03" w.c. relative to adjacent areas
- Externally vented
- Minimum of 12 ACPH
- Sink is at least 1 meter from C-PEC or directly outside the C-SCA

169) The C-PEC is certified as ISO 5 having less than 3,520 particles, greater than or equal to 0.5 microns, per cubic meter of air. (USP 797 - (4.2.3)
- Externally vented through HEPA filtration
- Certification is conducted every six months

170) An eyewash station and /or other emergency or safety precautions is readily available. (USP 800 - (5.3)

171) Personnel who compound hazardous CSPs are fully garbed with gowns, hair covers, shoe covers, 2 pair of chemotherapy gloves, and respiratory protection. (USP 800 - (7)
- Gowns are disposable and shown to resist permeability (USP 800 - 7.2)
- A second pair of shoe covers is donned before entering the HD compounding area. (USP 800 - 7.3)
- Appropriate eye and face protection is worn when there is a risk of spills or splashes. (USP 800 - 7.4)
- Gloves meet ASTM standard D6978 (USP 800 - 7.1)
- A NIOSH certified N-95 mask or more protective respiratory is worn when protection from HD exposure is required. (USP 800 - (7.5)

172) The following is doffed before entering areas where non-hazardous drugs are compounded. (USP 800 - (7.1) / (7.2) / (7.6)
- Outer pair of chemotherapy gloves
- Gown
- Outer shoe covers

173)		Pharmacies compounding Category 1 and Category 2 hazardous CSPs, deactivate, decontaminate, clean and disinfect the following daily: (USP 797 (7) - USP 800 (15). • Work surfaces, floors, sinks, pass through chamber • Sporicidal disinfectant applied Monthly	
174)		Category 3 pharmacies compounding hazardous CSPs, deactivate, decontaminate, clean and disinfect the following daily: (USP 797 (7) - USP 800 (15). • Work surfaces, floors, sinks, pass through chamber • Sporicidal disinfectant applied Monthly	
175)		Pharmacies compounding Category 1, Category 2, Category 3 hazardous CSPs deactivate, decontaminate, clean and disinfect the following monthly: (USP 797 (7) (Table 10) - USP 800 (15) • Walls, ceiling, doors, storage shelving, bins, and equipment	
176)		The PEC for pharmacies compounding Category 1 and Category 2 hazardous CSPs are deactivated, decontaminated, cleaned, and disinfected daily and between compounds with different components. (USP 797 (7) (Table 10) - USP 800 (15) • All agents used in the PEC are sterile • Sporicidal disinfectant applied Monthly	
177)		The PEC for Category 3 pharmacies compounding hazardous CSPs is deactivated, decontaminated, cleaned, and disinfected daily and between compounds with different components. (USP 797 (7) (Table 10) - (USP 800 (15) • All agents used in the PEC are sterile • Sporicidal disinfectant applied Monthly	
178)		The pharmacy has a spill kit readily available in all areas where hazardous drugs are routinely handled. (USP 800 - (16)	

Set Section N/A

Veterinary

179)		if compounded preparation (non-controlled) for verterinary use is not patient specific, then one of the following purposes must apply:(201 KAR 2:311) • emergency treatment; • Situations when a time delay would negatively affect a patient outcome; or • Diagnostic purposes;	
180)		Pharmacist shall receive a written, verbal, facsimile, or electronic requrest for a compound drug from a veterinary practioner that must indicate the formulation, strength and ordered quantity. (201 KAR 2:311)	
181)		A record of the request from a verterniary practioner for a compounded preparation shall be maintained pursuant to 201 KAR 2:171 and readily available for no less than 5 years. (201 KAR 2:076 Section 6(1) and (2)(a))	
182)		The compounded drug shall have a beyond use date. (201 KAR 2:311)	
183)		The veterinary institution or ambulatory unit shall maintain only an emergency stock supply. (201 KAR 2:311)	
184)		A label for non-patient specific compound shall be generated for the compunded drug and shall include: (201 KAR 2:311) • The name of the requesting veterinarian; • The designated name of the strength of the componded drug; • The quantity dispensed; • If for a specific patient and the patient is a food producing animal, the withdrawal time; • A lot or batch number of the compounded drug; • The beyond use date for the compounded drug; • The date the compounded drug is dispensed; • The pharmacy's, name, address, and telephone; • Any special storage requirements; • A notation stating "For veterinary use"; and • Any auxiliary label required for the compounded drug	

185)		A non-controlled substance compounded drug is dispensed by a veterinarian for emergency take home use when in his or her professional judgment, failure to provide the drug would result in potential harm to the patient. (201 KAR 2:311)	
186)		If dispensed from the veterinary institution or ambulatory unit, a compunded drug prescription for a veterinary patient shall be for up to a 14-day supply in accordance with the veterinarian prescription and dispensing labeling requirementsd as established in 201 KAR 16:600. (201 KAR 2:311)	
187)		A compounded drug containing a controlled substance shall only be compounded for patient specific dispensing from the pharmacy to the ultimate user. (201 KAR 2:311)	

Additional Information

***Inspector:**

***Start of Inspection:**

mm/dd/yyyy --:-- --

***End of Inspection:**

mm/dd/yyyy --:-- --

Type:

Follow Up:

Email Addresses to Receive Report:

***Email to Default Recipients:**

Notes:

Person Providing Information

Full Name: